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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,207	01/08/2001	Michael Stuke	HUBR1165 100	5279

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[REDACTED] EXAMINER

ROSSI, JESSICA

ART UNIT	PAPER NUMBER
1733	[REDACTED]

DATE MAILED: 08/13/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/647,207	STUKE ET AL.
	Examiner Jessica L. Rossi	Art Unit 1733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 7/14/03, RCE and Amendment C.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 23-39 and 45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 23-39 and 45 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All
  - b) Some \*
  - c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |                                                                                                               |                                                                              |
|---------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>14</u> . | 6) <input type="checkbox"/> Other: _____                                     |

## **DETAILED ACTION**

### ***Request for Continued Examination***

1. The request filed on 7/14/03 for an RCE under 37 CFR 1.114 based on parent Application No. 09/647,207 is acceptable and an RCE has been established. An action on the RCE follows.

### ***Response to Amendment***

2. This action is in response to the amendment filed on 7/14/03. Claims 40-44 were canceled. Claim 45 was added. Claims 23-39 and 45 are pending.
3. The rejection of claims 23-40 under 35 U.S.C. 103(a) as being unpatentable over Soane et al. (of record) in view of McReynolds (of record), as set forth in paragraph 7 of the previous office action, has been withdrawn in light of the added limitation of cooling up to 30 seconds (canceled claim 40; spec. p. 5, 1<sup>st</sup> paragraph) and Applicants arguments pertaining thereto.

### ***Claim Objections***

4. Claim 23 is objected to because of the following informalities: “a” should be deleted before “up” in line 12. Appropriate correction is required.
5. Claims 25 and 35 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Regarding claim 25, it fails to further limit claim 24 from which it depends because the limitations present in claim 25 are already present in claim 24 (acrylic polymers and polycarbonates). It is suggested to cancel claim 25.

Regarding claim 35, it fails to further limit claim 23 from which it depends because a heating at the temperature for at least 15 minutes is already claimed. It is suggested to cancel claim 35.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 38-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 38-39, it is unclear as to how cooling can be for at least 1 or 2 hours when claim 23, from which they depend, clearly states that cooling takes place for up to 30 seconds. This limitation in claim 1 has been interpreted to mean that cooling takes place for no more than 30 seconds, especially when read in light of the specification (p. 5, 1<sup>st</sup> paragraph) wherein cooling slowly (i.e. 1 or 2 hours) and cooling rapidly (i.e. up to 30 seconds) are clearly different embodiments. Applicants are asked to clarify. It is suggested to cancel these claims.

***Claim Rejections - 35 USC § 103***

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
9. Claims 23-29, 31-39, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over McReynolds (US 5882465; of record) in view of Soane et al. (US 6176962; of record) and optionally in view of Dixon et al. (US 5571369).

With respect to claim 23, McReynolds is directed to the adhesive-free bonding (a.k.a. thermal bonding) of microfluidic devices (column 4, lines 12-25). The reference teaches preparing a polymeric substrate 12 having microchannels 16, and applying a polymeric cover 18 to the substrate (Figure 1; column 3, lines 4-5, 29-33, 50-54, and 61-62; column 4, lines 21-22). The reference teaches thermally bonding the substrate and cover by heating the same while applying pressure thereto (column 4, lines 16-25). The reference also teaches the polymeric materials being thermoplastics such as **polymethylmethacrylate** and polycarbonate (column 3, lines 29-32). The reference is silent as to applying the cover to the substrate by uniform pressure ranging from 0.1-1000 kg/cm<sup>3</sup>, slowly heating to a temperature as high as the glass transition temperature of at least the substrate or cover, maintaining this temperature for at least 15 minutes, and cooling the substrate for up to 30 seconds.

It is known in the microfluidic device art to thermally bond microfluidic devices (column 5, lines 21-23) by preparing a polymeric substrate 12 having microchannels 21, 23, applying a polymeric cover 14 to the substrate by uniform pressure (Figures 5-6; column 2, lines 39-46 and 58-65), slowly heating the substrate and cover to 2-5°C above the glass transition temperature of the substrate and cover while applying pressure thereto, and maintaining them at this temperature for a sufficient period of time (column 2, line 63 – column 3, line 4). Soane teaches that heating to 2-5°C above the glass transition temperature allows for small irregularities in the surfaces to accommodate each other without jeopardizing the physical integrity of the channels while maintaining the substrate and cover at this temperature for a sufficient period of time allows for the polymer molecules to interpenetrate and bond (column 2, line 63 – column 3, line 4). Soane

also teaches the polymeric materials being thermoplastic, such as **polymethylmethacrylate** (column 9, line 65 – column 10, line 1).

It would have been obvious to the skilled artisan at the time the invention was made to apply the cover to the substrate of McReynolds by uniform pressure because such is known in the art, as taught by Soane, and this would ensure sufficient contact between the same (Soane; column 9, lines 30-36). As for a particular pressure range, McReynolds acknowledges that a particular pressure applied to the substrate and cover will depend on the nature of the polymeric material used (column 4, lines 33-36). Therefore, selection of a particular pressure range for the process of McReynolds would have been within purview of the skilled artisan at the time the invention was made depending on the polymeric material used wherein the skilled artisan would have been inclined to select a pressure range that produced sufficient contact between the substrate and cover without deforming the same.

It would have been obvious to the skilled artisan at the time the invention was made to slowly heat the substrate and cover of McReynolds to 2-5°C above their glass transition temperature and maintain the same at this temperature for a sufficient period of time because such is known in the art, as taught by Soane, and heating to this temperature would allow for small irregularities in the surfaces to accommodate each other without jeopardizing the physical integrity of the channels while maintaining this temperature for a sufficient period of time would allow for the polymer molecules to interpenetrate and bond (Soane; column 2, line 63 – column 3, line 4); it being noted that McReynolds teachings the applied temperature being dependent on the nature of the polymeric material used (column 4, lines 33-36) wherein both McReynolds and Soane teach using polymethylmethacrylate.

As for a specific temperature maintaining period, it is noted that Soane specifically points out that the temperature is held “**for a time period sufficient** to allow the polymer molecules to interpenetrate the polymeric surfaces of the substrate and cover and create a morphological bonding” (column 3, lines 1-4). The skilled artisan reading the Soane reference as a whole would have readily appreciated that selection of specific time period would have been determined by the polymeric materials used, such that the polymer molecules have sufficient time to interpenetrate the surfaces of the substrate and cover in order to create a satisfactory bond; it being noted that Soane (column 9, line 67 – column 10, line 1) teaches polymeric materials identical to those of McReynolds and the claimed invention (i.e. polymethylmethacrylate).

As for cooling, the skilled artisan reading the McReynolds reference as a whole would have appreciated that cooling would naturally commence upon termination of the heating step. However, it would have been obvious to the skilled artisan to rapidly cool the substrate and cover using a cooling source, such as cooling liquids/gases or a chill plate, because such are notoriously well known and conventional and this would expedite the manufacturing process; it being noted that the present invention and McReynolds both teach using polymeric materials such as polymethylmethacrylate and therefore one would only expect the substrate and cover of McReynolds to also be capable of being cooled for up to 30 seconds.

Selection of a particular “rapid” cooling time would have been within purview of the skilled artisan at the time the invention was made. However, thermal bonding of thermoplastic layers by heating to a desired temperature followed by rapid cooling (i.e. 7-16 seconds) of the same is known wherein such rapid cooling allows for accurate control of the degree of melting of

the layers, as optionally taught by Dixon (column 3, lines 53-56; column 4, lines 40-51; column 5, lines 43-46; column 6, line 4).

Regarding claims 24-25, McReynolds teaches the substrate and cover can be polycarbonate (column 3, lines 29-33).

Regarding claims 26-28, McReynolds teaches the microchannels having a width and/or depth ranging from 0.1-500 um (100 nm – 0.5 mm; column 2, lines 45-47).

Regarding claim 29, it would have been obvious to use the same polymeric material for the substrate and cover of McReynolds because such is known in the art, as taught by Soane (column 9, line 67 – column 10, line 1), and one reading the McReynolds reference as a whole would have appreciated that such is not critical to the invention.

Regarding claims 31-39 and 45, Applicants are directed to the rejection set forth for claim 23 above.

10. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over McReynolds, Soane, and optionally Dixon as applied to claim 23 above, and further in view of Parce et al. (US 6046056).

Regarding claim 30, McReynolds is silent as to at least the cover being transparent. It would have been obvious to the skilled artisan at the time the invention was made to use a transparent polymeric cover and/or substrate for those of McReynolds because such is known in the microfluidic device art, as taught by Parce (column 8, lines 57-66; column 9, lines 7-15), and this enables the microfluidic device to include a visual detection element (Parce; column 8, line 65 – column 9, line 3).

***Response to Arguments***

11. Applicant's arguments filed 7/14/03 have been fully considered but they are not persuasive.
12. On page 5 of the arguments, Applicants argue that Soane teaches away from cooling for up to 30 seconds, as claimed in present claim 23.

The examiner points out that Soane is now only being used to show that heating 2-5°C above the glass transition temperature of a thermoplastic material is known in the art for facilitating thermal bonding two thermoplastic materials.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jessica L. Rossi** whose telephone number is **703-305-5419**. The examiner can normally be reached on M-F (8:00-5:30) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael W. Ball can be reached on 703-308-2058. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Jessica L. Rossi  
Patent Examiner  
Art Unit 1733



Michael W. Ball  
Supervisory Patent Examiner  
Technology Center 1700